REMARKS

Claim Rejections – 35 U.S.C. § 112

a. Claims 1, 2, 4 and 5 are rejected under 35 U.S.C. § 112, second paragraph, for allegedly being indefinite. According to the Examiner, Claims 1, 2, 4 and 5 are deemed to be incomplete because the claims are drawn to a "nucleic acid assay," which is a method, but the claims do not list any steps.

Applicants respectfully traverse this basis for rejection.

Applicants respectfully submit that the Examiner has misinterpreted the meaning of the term "assay" as used in the subject application. Although "assay" may refer to a method for identifying a substance, the term is used in claim 1 to refer to a set of reagents used as a system for identifying a substance, in this case a specific sample nucleic acid sequence. *See* page 20, lines 1-15. Each of the reagents is listed under (a)-(e) in claim 1. The written description clearly indicates that the assay is distinct from the method of its use. *Contrast* page 5, lines 13-15 ("In one aspect of the present invention, there is provided a nucleic acid assay for detecting the presence of a specific sample nucleic acid sequence in a sample suspected of the containing the same") *with* page 7, lines 1-3 ("In another particular aspect of the present invention, there is provided a method of detecting the presence of a specific sample nucleic acid sequence in a sample suspected of containing the same"). Indeed, the Examiner has restricted the method of claims 22-27 from the assay of claims 1-21 for being directed to a different invention.

Accordingly, Applicants submit that claims 1, 2, 4 and 5 are not indefinite, and reconsideration of this basis for rejection is respectfully requested.

b. Claims 1, 2, 4 and 5 are rejected under 35 U.S.C. § 112, first paragraph, for allegedly failing to comply with the written description requirement. According to the Examiner:

> The method of said claims requires the use of matrix and probe oligonucleotides. A review of the specification fails to find where applicant has provided an adequate written description of the essential starting materials and reaction conditions so as to reasonably suggest that applicant was in possession of the generic method at the time of filing. In particular, it is noted that the disclosure has not been found to set forth any SEQ ID NO. for any matrix/dendrimer or for any probe. . . . It [thus] appears that applicant is attempting to satisfy the written description requirement of 35 USC 112, first paragraph, through obviousness. Obviousness, however, cannot be relied upon for satisfaction of the written description requirement.

Applicants respectfully traverse this basis for rejection.

A description as filed is presumed to be adequate, unless or until sufficient evidence or reasoning to the contrary has been presented by the examiner to rebut the presumption. *See In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971). The examiner, therefore, must have a reasonable basis to challenge the adequacy of the written description. The examiner has the initial burden of presenting by a preponderance of evidence why a person skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims. *See Wertheim*, 541 F.2d 257, 263, 191 USPQ 90, 97 (CCPA 1976). An applicant shows possession of the claimed

invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. *See Lockwood v. American Airlines, Inc.,* 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997).

Each of the pending claims is directed to nucleic acid assay for detecting the presence of a specific sample nucleic acid sequence in a sample suspected of the containing the same, said nucleic acid assay comprising:

(a) a matrix comprising at least one first site for receiving an invader oligonucleotide and at least one second site for receiving a probe oligonucleotide;

(b) at least one invader oligonucleotide for attaching to the first site of the matrix, said invader oligonucleotide having an invader nucleic acid sequence for binding to a first portion of the sample nucleic acid sequence;

(c) at least one probe oligonucleotide for attaching to the second site of the matrix, said probe oligonucleotide having a first probe nucleotide portion for binding to a second portion of the sample nucleic acid sequence and a second probe nucleotide portion which does not bind to the sample nucleic acid sequence;

(d) a first disassociating agent for disassociating the second probe nucleotide portion of the probe oligonucleotide from the first probe nucleotide portion upon the concurrent binding of the invader nucleic acid sequence of an invader oligonucleotide to the first portion of the sample nucleic acid sequence and the first probe nucleotide portion for binding to the second portion of the sample nucleic acid sequence; and

(e) detection means for detecting the degree to which the second probe nucleotide portion of the probe oligonucleotide has disassociated from the first probe nucleotide portion thereof.

Each of the steps of the claims is clearly described in the application as originally filed, thus evidencing that Applicants were in possession of the claimed invention at the time of filing. For example, the matrix in step (a) is described at page 13, line 1 to page 14, line 15; the invader oligonucleotide in step (b) is described at page 14, lines 16-19; the probe oligonucleotide in step (c) is described at page 14, line 19 to page 15, line 12; the disassociating agent in step (d) is described at page 15, line 13 to page 16, line 7; and the detection means in step (e) is described at page 17, line 17 to page 18, line 21. Implementation of the system is described at page 16, line 8 to page 17, line 2, and exemplified in Examples 1 and 2. As such, contrary to the Examiner's assertion, Applicants have "provided an adequate written description of the essential starting materials and reaction conditions so as to reasonably suggest that applicant was in possession of the generic method at the time of filing."

According to the Examiner, "the disclosure has not been found to set forth any SEQ ID NO. for any matrix/dendrimer or for any probe." However, Applicants note that there is no requirement that SEQ ID NOs be included to provide an adequate written description of claims directed matrices, probes, etc. As discussed above, Applicants have provided descriptions of each of the claim components and their interaction for use in a detection system. One of skill in the art could design specific embodiments of the

claimed matrix, invader oligonucleotide and probe oligonucleotide using routine knowledge in the art, e.g., hybridization reactions. As such, there is no need to include specific nucleotide sequences for these claim components, and thus SEQ ID NOs are not required.

Accordingly, Applicants submit that claims 1, 2, 4 and 5 comply with the written description requirement, and reconsideration of this basis for rejection is respectfully requested.

CONCLUSION

It is believed that claims 1, 2, 4 and 5 are now in condition for allowance, early notice of which would be appreciated. Applicants respectfully request that each of the restriction requirements be withdrawn and the unexamined claims be rejoined and all the claims passed to issuance. No fees are believed due at this time. If, however, any fees are due, the Commissioner is authorized to charge any such fee to our Deposit Account No. 50-3329. Please contact the undersigned if any further issues remain to be addressed in connection with this submission. Also, please note new counsel's correspondence address and docket number set forth herein.

Dated: January 12, 2010

Respectfully submitted,

/Kenneth M. Zeidner, Reg. No. 64700/
Kenneth M. Zeidner
Reg. No. 64,700

Diehl Servilla LLC
77 Brant Avenue, Suite 210
Clark, New Jersey 07066
TEL (732) 815-0404
FAX (732) 815-1330
Attorneys for Applicants